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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,643	07/13/2000	Thomas L. Meredith	N-6089RSM	4680

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WADDEY & PATTERSON
414 UNION STREET, SUITE 2020
BANK OF AMERICA PLAZA
NASHVILLE, TN 37219

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/615,643

Applicant(s)

MEREDITH, THOMAS L.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) 19, 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/30/02 has been entered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18,32, drawn to a method of making a bone composite, classified in class 264, subclass 425.
- II. Claims 19,21-31, drawn to bone tissue composite, classified in class 623, subclass 23.63.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different products not comprising cortical bone. Additionally, it can

be said that the product as claimed can be made by another materially different process not requiring a curing or solidifying step.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Phillip Walker on 12/4/02 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-18,32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19,21-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. The drawings must show every feature of the invention specified in the claims. Therefore, the "bone pin, screw or prosthesis" must be shown or the feature(s) canceled from the claim(s). No new matter may be introduced in the required drawing.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should *avoid using phrases which can be implied*, such as, "The disclosure concerns," "**The present invention**," "The disclosure describes," etc.

The abstract of the disclosure is objected to because implied language should not be used in the abstract. Correction is required. See MPEP § 608.01(b).

Response to Amendment
and 12/04/02

ABP
12/9/02
The revised declaration filed on 9/30/02^{and 12/04/02} under 37 CFR 1.131 is effective to overcome the Boyce '187 reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is not clear as to what applicant is referring to as an "organic matrix". According to the specification, (pages 11 lines 15-20 and page 12, lines 1,2) the applicant mentions adhesive materials are used as matrices. However, it should be noted that natural bone tissue also includes "organic

material" and can be said to be in matrix form. Thus it is unclear if applicant means that something is added or just that the bone tissue includes the "organic matrix."

With respect to claim 8, there are various measurements that relate to size, i.e. width, length, thickness. It is not clear what dimension applicant is referring to.

Claims 15,16 recites the limitation "the cyanoacrylates " in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (4645503). Lin et al. disclose that bone tissue can be used in forming a bone composite, col. 3, lines 16-25. Since Lin discloses the bone is in the form of chips, it is inherently ground bone tissue. Lin additionally discloses the binder with the implant material are shaped or "molded" and cured by heating in the bone site, thus forming a solid structure, col. 6, lines 42-51. It can be construed that the binder forms an organic matrix with the bone chips. Lin also discloses that the material can be solid or in block form, col. 6, lines 10,11.

Claims 1-3,8-12,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowd et al. (5507813). Dowd et al. disclose the use of bone particles with binders to form a bone composite, col. 1, lines 47-50. Dowd also discloses the particles are obtained by milling or "grinding" into a size within the range of 125 to 850 microns, col.

2, lines 51-54. The bone used can be cortical and demineralized, col. 3, lines 19,20, 26-29. Dowd additionally discloses the bone particles are mixed with adhesives, which inherently would form an organic matrix, col. 3, lines 66,67. The composite material is soaked with a binder and then molded, col. 4, lines 58-67. Dowd discloses a pressure within 14.7 to 30,000 psi to mold the composite, col. 5, lines 19-24. The material cures after it is implanted and hydrated. Binders can be applied before or after shaping or "molding," col. 4, lines 2-4. The bone composite can be a pin or screw, col. 7, lines 23,24.

Claims 1-3,10,12,14,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyle (5061286). Lyle discloses a method of forming a bone composite by grinding bone tissue and demineralizing the bone, col. 3, lines 9-12. Lyle also discloses the particles can contain an organic matrix in the form of a collagen lattice, col. 3, lines 48-53,66. The bone used can be cortical, col. 3, lines 5-8. Lyle additionally discloses the bone particles are mixed with the binder cyanoacrylate and sprayed on, col. 4, lines 15-23. Binders can be applied before molding, col. 5, lines 48-58. The bone and binder can also be combined as a powder mixture which is cured by heating and then applied as a coating, such that it can be applied on the prosthesis in layers, col. 6, lines 3-22. The composite forms a solid structure by being molded onto a prosthesis.

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Glimcher et al. (5565502). Glimcher et al. disclose a method of using bone tissue by grinding the bone into ground tissue of a size between 125-850 microns, col. 7, lines 16-19.

Glimcher also discloses a binder, such as a cyanoacrylate can be added with the bone

particles, col. 11, lines 57-60. Glimcher also teaches the bone composite can be applied on the surface of prostheses (col. 11, lines 61-64, col. 12, lines 35-39) which inherently implies the bone composite is molded and pressure is applied by the device delivering or applying the material. The bone composite is molded to the shape of the prostheses and inherently the composite will solidify after application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. '813. Dowd et al. is explained supra. However, Dowd et al. do not disclose the percentage of cortical bone in the bone tissue. It would have been an obvious matter of design choice to a person of ordinary skill in the art to use greater than 50% or up to 95% cortical bone tissue as the specific percentage used in the Dowd et al. composite because Applicant has not disclosed that any specific percent provides an advantage over another, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the percent of cortical bone as taught by Dowd et al. or the claimed greater than 50% or up to greater than 95% cortical bone because all percentages of cortical bone particles will still form a solid bone composite.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle '286 in view of Bonutti (6132472). Lyle is explained supra. Lyle does disclose adding

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attachment agents to the bone particles, col. 4, lines 4,5. However, Lyle does not disclose the addition of fibrin in the bone composite. Bonutti teaches that fibrin can be added to bone material used as an implant, col. 3, lines 61-67. It would have been obvious to a person of ordinary skill in the art to use fibrin in the bone composite as taught by Bonutti in the Lyle composite because fibrin is tacky and is capable of holding particles together.

Claims 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle '286. Lyle is explained supra. However, Lyle does not disclose the type of cyanoacrylate used. It would have been an obvious matter of design choice to a person of ordinary skill in the art to use ester chain or long chain cyanoacrylates as the specific cyanoacrylate binder used in the Lyle composite because Applicant has not disclosed that any specific cyanoacrylate provides an advantage over another, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the cyanoacrylate taught by Lyle or the claimed ester or long chain cyanoacrylate binders because both types hold together the bone particles.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. '813. in view of Bonutti (6132472). Dowd et al. '813. is explained supra. However, Dowd et al. do not disclose using a die to shape and mold the bone particles. Bonutti teaches that a die is used to form the bone tissue into the desired shape, col. 11, lines 13-36. It would have been obvious to a person of ordinary skill in the art to use a die to

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mold the bone composite as taught by Bonutti in the Dowd et al. composite because this would produce a composite having a preset or known dimension which is desirable.

Response to Arguments

Applicant's arguments with respect to claims 1 and 32 have been considered but are moot in view of the new ground(s) of rejection.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino
December 6, 2002

TC 3700, AU 3738


Paul Prebilit
Primary Examiner

